Public Health Committee Testimony – March 11, 2011

HB 5610: AN ACT CONCERNING THE DUTIES OF A PHARMACIST WHEN FILLING A PRESCRIPTION USED FOR THE TREATMENT OF EPILEPSY OR PREVENTION OF SEIZURES.

Representative Ritter, Senator Gerratana and the Public Health Committee, thank you for the opportunity to express my opposition to HB 5610 as it is currently written. My name is Thomas Buckley, Assistant Clinical Professor at the University of Connecticut School of Pharmacy. Although I believe there are numerous reasons for opposing this bill, I will limit my rationale for opposition to two main points:

(1) Last year in my testimony I urged the committee to wait for the results of the comparative effectiveness research study funded by the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services. The results of the "*Comparative Effectiveness of Medications in Patients with Epilepsy"* were released on February 15th, and I will summarize their conclusions for you today. I have included the link to the entire report in my written testimony and submitted the full report as an attachment to my testimony through your email site.
AHRQ report link:
http://www.effectivehealthcare.ahrq.gov/ehc/products/159/626/Epilepsy%20Report.pdf

Over the past decade there have been new antiepileptic drugs that have been approved for use by the FDA, but studies comparing benefits and harms of older versus newer drugs have yielded inconclusive results. In addition, there have been conflicting views from professional organizations on comparative benefits and harms of brand versus generic or generic versus generic formulations of antiepileptic drugs. Therefore, AHRQ requested a comparative effectiveness review from one of their 12 Evidence-based Practice Centers (EPCs); the research was conducted by the University of Connecticut/Hartford Hospital EPC. The EPC reviews all relevant literature to produce evidence reports used to develop coverage decisions, quality measures and clinical guidelines.

Nearly 5800 citations were identified for this research, reflecting the comprehensive nature of the analysis, which had 2 focus areas: newer versus older antiepileptics (which we will not address since it is not relevant to this bill) and a comparison of innovator (brand) to generic and generic to generic utilization.

The investigators found **no difference** with regard to efficacy or safety between innovator (brand) antiepileptic medications and their respective generic versions, and **no difference** between generic versions of the same chemical entity. To quote the efficacy section of the report: "For the comparison of innovator antiepileptic medications to their respective generic versions we found that seizure occurrence and frequency was similar

between groups in controlled clinical trials. In addition, there were no differences between innovator antiepileptic medications and their respective generic versions in terms of total withdrawals or withdrawals due to lack of efficacy in controlled clinical trials." From the report's safety analysis: "The withdrawals due to adverse events were similar between the innovator and generic versions of antiepileptic medications; no significant differences were noted between innovator and generic antiepileptic medications for evaluated adverse events."

(2) The results of the AHRQ report lead me to my second point. This bill unnecessarily changes the pharmacy practice act; and while I appreciate the spirit of your intent, to ensure that medication decisions are made by the appropriate entities - the prescriber, patient, and pharmacist - this legislation will in fact do the opposite. A prescriber in Connecticut can already determine and request specific medication therapy for a patient. Pharmacists serve as the medication expert, discussing therapies and working with prescribers and patients to ensure that optimal medication is provided and adhered to.

Generic substitution is a well-established practice, providers and patients should have confidence in the current FDA system in which generic drugs are approved and evaluated; this was validated by the findings in the AHRQ report. Any unnecessary mandate would inhibit access to prescription drugs that provide significant cost savings to consumers, health plans, and employers. Furthermore, adopting legislation that pertains to one type of medical problem, and the drugs developed to specifically treat it encourages similar initiatives for other classes of medications.

Behavioral research has shown that patients who have confidence in their therapy, that its benefits outweigh any risks, have higher rates of adherence to their therapy which leads to optimal therapeutic outcomes. Setting precedent with this legislation may undermine patients' confidence with generic formulations of any medication.

Therefore, I urge the committee to closely review the AHRQ comparative effectiveness report, and to recognize this is unnecessary legislation that, in fact, may threaten the health and welfare of the public, and interfere with the critical prescriber-patient-pharmacist relationship. If you have any questions regarding these comments or if I can provide you with additional information, I invite you to contact me at thomas.e.buckley@uconn.edu.

Sincerely,
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